

REMARKS

Claim 51 has been amended to recite that the first and second analytes are present in "pre-determined amount[s] . . . based on the pre-determined range of analyte concentration" and that "the pre-determined amount of the . . . reagent such that the detectable response is" inversely or directly proportional to the analyte concentration, respectively. In addition, claim 51 has been amended to recite the binding relationships between the analyte, the labeled indicator reagent, and the first and second reagents. Support for these amendments can be found in the specification at, for example, page 8, line 2 - page 12, line 15; page 13, lines 1-18; page 21, line 20 - page 41, line 25 - page 43, line 12; and page 46, line 18 - page 47, line 26; and in Examples 2-9.

Claim 52 has been amended to depend from claim 51 to correct an obvious typographical error. This amendment does not change the scope of the claim in any way.

Claims 68-76 have been added. Support for these claims can be found in the specification at, for example, page 8, line 2 - page 12, line 15; page 13, lines 1-18; page 21, line 20 - page 41, line 25 - page 43, line 12; and page 46, line 18 - page 47, line 26; and in Examples 2-9.

INTERVIEW SUMMARY

The Examiner is thanked for the courtesies extended during the telephonic interview conducted with the undersigned on October 2, 2008. During the interview, amendments to the claims to overcome the rejection for anticipation were discussed. Agreement was reached that an amendment to claim 51 to recite "pre-determined amounts" of the first and second reagents "such that the detectable response is" inversely or directly proportional to the analyte concentration, respectively, would obviate the rejection of the claims as

anticipated. The claims have been amended as agreed. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 112, ¶ 2

Claims 51-60 have been rejected as indefinite. (Paper No. 20070604 at 2.) It is the view of the Patent Office that the claims "are vague because it doesn't appear that the different reagents bind to each other, i.e. the binding relationship between the various reagents is not clearly recited." (*Id.*)

Claim 51, from which claims 52-60 depend, has been amended to recite the binding relationships between the analyte, the labeled indicator reagent, and the first and second reagents. With these amendments, it is submitted that one of ordinary skill in the art, when reading claims 51-60 (as amended) in light of the specification would readily recognize the particular area set out and circumscribed by the claims. Nothing more is required. Accordingly, it is respectfully submitted that the rejection of claims 51-60 has been rendered moot and withdrawal is requested.

Claims 68-76 have been added. Claim 68, from which claims 69-76 depend, also recites the binding relationships between the analyte, the labeled indicator reagent, and the first and second reagents. One of ordinary skill in the art, reading claims 68-76 in light of the specification would readily recognize the particular area set out and circumscribed by the claims. Accordingly, it is respectfully submitted that claims 68-76 also fully comply with the requirements of 35 U.S.C. § 112, ¶ 2.

35 U.S.C. § 102(e)

Claims 51-60 have been rejected as anticipated by Fitzpatrick et al., U.S. Patent 5,451,504 ("*Fitzpatrick*") on

light of May et al., WO 88/08534. (Paper No. 20080604 at 3.) Applicants respectfully traverse.

In making the rejection, the Examiner equates *Fitzpatrick's* mobilization zone with the sample application zone of the invention, *Fitzpatrick's* trap zone with the test zone of the invention, and *Fitzpatrick's* detection zone with the reference zone of the invention. (See Paper No. 20080604 at 3-4.) The Examiner characterizes the trap zone of *Fitzpatrick* as having "an immobilized ligand (that binds to the labeled reagent when analyte is not present producing a signal that is inversely proportional to the concentration of analyte)" and that the detection zone "provides for detection of a receptor-analyte complex which positively correlates with the presence of analyte in the sample." (*Id.* at 4.)

The instant claims have been amended to recite "pre-determined amount[s of the first and second reagents] . . . based on the pre-determined range of analyte concentration" and that "the pre-determined amount of the . . . reagent such that the detectable response is" inversely or directly proportional to the analyte concentration, respectively. *Fitzpatrick* discloses a membrane strip with three general zones: a mobilization zone, a trap zone, and a detection zone. (See Abstract; col. 1, lines 46-69; col. 2, lines 15-16; and col. 4, line 50 - col. 9, line 15.) *Fitzpatrick* is silent as to any detectable response in its trap zone. This trap zone "comprises immobilized ligand that will bind, i.e., trap, free receptor moving through the trap zone, but will not bind receptor bound in a receptor-analyte complex." (col. 6, lines 39-41.) In nearly two full columns of text devoted exclusively to the trap zone, *Fitzpatrick* says absolutely nothing about any detectable response, much less any inversely proportional response.

Moreover, *Fitzpatrick* discloses only that the response in the detection zone has a positive correlation to the presence

of the analyte. *Fitzpatrick* actually emphasizes the desirability of a simple signal that only detects a positive result.

Positive detection means that signal positively correlates with the presence of analyte in a sample. **A positive correlation is advantageous because it is psychologically satisfying that the presence of signal or increase in signal intensity indicates presence of analyte in a sample.** Both sophisticated diagnostic laboratories and non-technical personnel **benefit from the use of an assay in which a signal means only a positive result because such results are not susceptible to misinterpretation, as may occur when the absence of signal indicates presence of analyte.**

(Col. 8, lines 19-29 (emphasis added).)

Moreover, *Fitzpatrick* is concerned only with the detection of "the presence [or absence] of an analyte in a sample" (Abstract) and nothing more. *Fitzpatrick* is completely silent as to any proportional response in the trap or detection zones, as is required in the claimed reference zone. In the sole example in *Fitzpatrick*, the results are reported only as negative or positive for the detection of the analyte. (See Table 1 and col. 13, lines 21-48.)

Thus, *Fitzpatrick* does not disclose any proportional response in its detection zone or any inversely proportional response in its trap zone. Given this gap, it is not surprising that *Fitzpatrick* is also silent as to any "pre-determined amount[s of a first and second reagents] . . . based on the pre-determined range of analyte concentration" or that "the pre-determined amount of the . . . reagent such that the detectable response is" inversely or directly proportional to the analyte concentration, respectively, as claimed.

Accordingly, *Fitzpatrick* does not disclose each and every element of the claimed invention. For the foregoing reasons, it is submitted that the rejection has been rendered moot. Withdrawal of the rejection is respectfully requested.

Claims 68-76 have been added. Claim 68, from which claims 69-76 depend, also recites "pre-determined amount[s of a first and second reagents] . . . based on the pre-determined range of analyte concentration" and that "the pre-determined amount of the . . . reagent such that the detectable response is" inversely or directly proportional to the analyte concentration, respectively. Accordingly, it is respectfully submitted that claims 68-76 are also not anticipated by *Fitzpatrick*.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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